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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,957	06/18/2001	Rose Ramon Botella Mesa	229752001300	3466

7590 09/09/2005

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1633

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Handwritten mark

Office Action Summary

Application No.

09/763,957

Applicant(s)

BOTELLA MESA ET AL.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2005 and 10 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,9,11-15 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,9,11-15 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to an amendment filed 3/9/05 and 6/10/05. Claims 2-6, 8, 10, 16-18 and 25 have been cancelled. Claims 1, 7, 11, 15, 19 and 23 have been amended. Claims 1, 7, 9, 11-15 and 19-24 are pending in the application. Applicants indicate that a request for corrected filing receipt has not been made in the application despite a request to do so. A copy of the request has been forwarded with this office action to OIPE for processing.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. The new grounds of rejection herein were necessitated by amendment and, therefore, this action is final.

Claim Objections

Claims 11-14 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to the claim numbers in the alternative (applicants do not refer to claims 22-24 in the alternative). See MPEP § 608.01(n). Accordingly, the claims not been further treated on the merits.

Response to Argument

Applicants indicate in the response filed 3/9/05 that they have amended the claims to overcome this objection. However, the claims have not been properly amended and still refer to the multiple claims in the alternative.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 9, 11-15 and 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment.**

The limitation that the nucleotide sequence is "at least residues +1 to -368" or a homolog of, complement of or sequences capable of hybridizing to "at least residues +1 to -368" has been added to claim 1, 7 and 15. Applicant has not indicated where support for this limitation is found. The examiner has been unable to find literal support in the originally filed specification for the term "at least residues +1 to -368" specifically because SEQ ID NO:3 comprises amino acids 1 to 2474. Therefore, the limitation of "at least residues +1 to -368" is impermissible
NEW MATTER.

Claims 1, 7, 9, 11-15 and 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment.**

In claim 1, 7 and 15, applicants claim a genus of sequences that are nucleotide sequences that "define a promoter", said sequence with at least 90% similarity to SEQ ID NO:3 or to +1 to -368 or a complement of these sequences or a sequence of nucleotides that hybridize to these sequences under stringency conditions of 2X SSC, 0.1% w/v SDS and 45°C.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

Applicants recite a broad and diverse genus of sequences that are nucleotide sequences that "define a promoter", said sequence with at least 90% similarity to SEQ ID NO:3 or to +1 to -368 or a complement of these sequences or a sequence of nucleotides that hybridize to these sequences under stringency conditions of 2X SSC, 0.1% w/v SDS and 45°C. Functionally, applicants disclose that sequences that "define a promoter" "confers, activates or enhances expression of a structural gene or other nucleic acid in a plant cell" (see page 16, paragraph 5). Structurally, applicants disclose the sequence of pGEL-1 (SEQ ID NO:3). pGEL-1 comprises the promoter from mung bean ACC synthase that directs expression of a protein encoded by a sequence with 100% identity to SEQ ID NO: 1, primer pairs 4 and 5 that are used to isolate the promoter from mung bean. To characterize the promoter, applicants generate a series of seven

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serial deletions of the mung bean ACC synthase promoter region (page 36). A general decline in activity in the shorter promoters is detected in immature and mature leaf tissue but not evidently in any other tissues (page 37).

By reciting sequences with 90% homology to SEQ ID NO:3 or the fragment comprising +1 to -368, applicants recite a broad genus of promoters that can differ in any of 10% of the nucleotides of SEQ ID NO:3. Furthermore, by claiming sequences hybridizing under medium stringency conditions (according to page 13, 6X SSC, 0.1% w/v SDS and 45°C), the relationship between the structure of the sequence and its function becomes unclear. However, applicants do not provide the structural requirements of the sequences of SEQ ID NO:3 that “confers, activates or enhances expression of a structural gene or other nucleic acid in a plant cell”. The specification provides a single reference sequences without identifying relevant characteristics or structural-functional relationships. Nor does the art teach the acc synthase promoter from mung bean nor does it teach domains or motifs required for promoter activity by the acc synthase promoter. Thus neither the specification nor the prior art teach the structural requirements of sequences with at least 90% similarity to SEQ ID NO:3 or to +1 to -368 or a complement of these sequences or a sequence of nucleotides that hybridize to these sequences under stringency conditions of 2X SSC, 0.1% w/v SDS and 45°C that encodes a promoter. Given the large size and diversity of the recited sequences, the absence of disclosed or art recognized correlations between structure and function and the large number of potential sequences or homologs, it must be considered that any sequence with promoter activity in a plant cell must be empirically determined. A person of ordinary skill in the art could not predict the operability of the species that would be isolated of sequences with at least 90% similarity or a complement of this

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sequence of a sequence of nucleotides that hybridize to SEQ ID NO:3 under stringency conditions of 2X SSC, 0.1% w/v SDS at 45°C. By disclosing pGEL-1, the applicants have not reduced to practice the claimed invention and the relationship between structure and function is unclear. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Response to Amendment-35 USC 112, first paragraph

Applicants traverse the claim rejections under 35 U.S.C. 35 USC 112, first paragraph on page 7 of the amendment filed 3/9/05. Applicants argue that the claims as amended provide the requisite structural characteristic and have deleted functional characteristics. Therefore, applicants request the rejection be withdrawn.

Applicant's arguments filed 3/9/05 have been fully considered but they are not persuasive. Applicants have not provided sufficient structural characteristics of the recited genus of sequences such that a person of skill in the art would be able to identify those sequences that "define a promoter". Applicants have disclosed a single reference sequence but have not provided the relevant structural characteristics that are required of the sequences so that it "confers, activates or enhances expression of a structural gene or other nucleic acid in a plant cell". A person of ordinary skill in the art could not predict the operability of the species that would be isolated of sequences with at least 90% similarity or a complement of this sequence of a sequence of nucleotides that hybridize to SEQ ID NO:3 under stringency conditions of 2X SSC, 0.1% w/v SDS at 45°C. Adequate written description requires more than a mere statement

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that the sequence is part of the invention and a reference to a potential method for isolating it.

Therefore, the specification has failed to describe the genes such that the nexus of structure and function is apparent.

Conclusion

Claims 1, 7, 9, 11-15 and 19-24 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1633

August 25, 2005


JAMES KETTER
PRIMARY EXAMINER